Please add new claims 52 and 53 as follows:

AY

52. (New) A biomedical skin electrode comprising a skin contactable bioadhesive, the skin contactable bioadhesive comprising a composition of claim 19.

53. (New) A wound dressing comprising a skin contactable bioadhesive, the skin contactable bioadhesive comprising a composition of claim 19.

REMARKS

In the above-identified Office Action, the Examiner has rejected claims 19, 21-47 and 51 under 35 U.S.C. §112 as being indefinite for use of the phrase "other than water". Applicant has amended claims 19, 21-22 and 30 so that the parentheses have been deleted. However, Applicant declines to delete the phrase "other than water". Applicant notes that pursuant to MPEP 2173.05(i), negative limitations, while they were previously indefinite, are now considered acceptable under the requirements under 35 U.S.C. §112. Accordingly, Applicant requests withdrawal of this rejection. Applicant also notes that it has a U.S. application serial number 09/771,004 in which the identical phrase appears in the claims. This application has recently been allowed. Applicant would appreciate the opportunity to maintain conformity between the applications on this point. This application is in the same art unit as the subject application.

In addition, claim 51 appears to have been rejected as indefinite for merely reciting a use without any active or positive steps. Applicant has cancelled claim 51, resubmitting it as claims 52 and 53 and as such believes that the new claims should be acceptable.

Claims 19-47 and 51 have been rejected under 35 U.S.C. §103(a) as being obvious over

the patent to Dietz et al. The Examiner has stated that it would have been obvious to apply the teachings of Dietz et al. to provide bioadhesive composition suitable for medical applications.

Applicant notes that the subject claims are product by process claims and therefore the process steps become important.

The subject invention comprises a bioadhesive composition which is the product of polymerising a homogeneous aqueous reaction mixture. The term is defined at page 7, lines 10 to 16, of the application, and refers to a substantially solubilised system in which substantially no phase segregation occurs prior to the polymerisation reaction.

In contrast, the compositions generally described in both Dietz references are the products of polymerising microemulsions which are phase-segregated at all stages prior to polymerisation (e.g. Abstract in each reference).

As far as the specific examples of the Dietz references are concerned, Example 38 of each reference describes a bioadhesive composition ("PSA") which is the product of polymerising a microemulsion aqueous reaction mixture comprising 21.2% by weight of NaAMPS (an ionic watersoluble monomer), 0% by weight of a plasticiser other than water, 14.9% by weight of poly(ethylene oxide) acrylate and N-vinyl pyrrolidone (non-ionic water-soluble monomers), and 21.2% by weight of water (comprising half of the total "AMPS" component constituting NaAMPS and water), together with the following additional components: 33.8% be weight iso-octyl acrylate (a hydrophobic monomer); 0.37% by weight of a photoinitiator; and 8.8% by weight of a surfactant.

These Examples appear to be the closest specific teaching in the references. Each is deficient in that it does not teach:

- the use of a homogeneous reaction mixture; and

- the use of 10% to 50% by weight of at least one plasticiser other than water.

In summary, there are two clear points of difference with the present claims. The Dietz references completely fail to teach the use of a homogeneous reaction mixture, and the vague mention of "plasticisers" in a long list of possible additives (WO95/20634, page 17, line 21; WO97/05171, page 18, line 9) is wholly insufficient as an enabling teaching of the use of 10 to 50% of at least one plasticiser other than water.

There is absolutely no suggestion or teaching in the Dietz reference to substitute the phase-segregated pre-polymerisation mixture of the closed prior art (Example 38 of each reference) with the homogeneous pre-polymerisation mixture with added plasticiser according to the present invention, in the expectation of achieving a bioadhesive composition, let alone one which makes available the advantages of the present invention. Rather, the Dietz references focus exclusively on microemulsion pre-polymerisation mixtures.

It is believed that the present invention provides bioadhesive compositions having superior skin adhesion properties, by a mechanism whereby the components are held in a substantially solubilised form right up to the point of formation of the polymer, so that any tendency of the components to phase-separate is effectively suppressed. At the point of polymerisation a three-dimensional polymeric matrix is believed to lock the water molecules into its structure, so that the water then ceases to perform a solubilising role.

It has been found that the surfaces of the polymerised body according to the present invention typically have well defined regions of relatively less hydrophilic (relatively hydrophobic) domains embedded in a relatively hydrophilic matrix in which the water is predominantly contained. In other words, the polymerised body is typically non-bicontinuous, again in contrast to the materials described in the prior art.

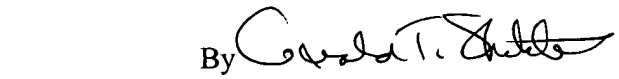
It is believed that it is largely the presence of non-bicontinuous, relatively more hydrophilic and relatively less hydrophilic, domains at the surface of the bioadhesive body that gives rise to the superior skin adhesion properties of the compositions of the present invention, particularly the adhesion to greasy skin (e.g. naturally greasy skin or skin which has residual greasy materials on it, such as cremes or ointments).

Reconsideration and reexamination are respectfully requested.

With the above amendments and remarks, this application is considered ready for allowance and Applicant earnestly solicits an early notice of same. Should the Examiner be of the opinion that a telephone conference would expedite prosecution of the subject application, he is respectfully requested to contact the undersigned at the below listed number.

Respectfully submitted,

Welsh & Katz, Ltd.

By 
Gerald T. Shekleton
Registration No. 27,466

Date: February 24, 2003

WELSH & KATZ, LTD.
120 South Riverside Plaza
22nd Floor
Chicago, Illinois 60606-3913
Telephone: 312/655-1500

MARKED UP VERSION TO SHOW CHANGES MADE

IN THE SPECIFICATION

19. (Amended) A bioadhesive composition formed by polymerising a homogeneous aqueous reaction mixture comprising from about 5% to about 50%, by weight of the reaction mixture, of at least one ionic water soluble monomer, from about 10% to about 50%, by weight of the reaction mixture, of at least one plasticiser [(]other than water[)], up to about 50%, by weight of the reaction mixture, of at least one non ionic water soluble monomer, up to about 40%, by weight of the reaction mixture, of water, up to about 10%, by weight of the reaction mixture, of at least one surfactant and from about 1% to about 30%, by weight of the reaction mixture, of at least one hydrophobic monomer and/or polymer.

21. (Amended) A bioadhesive composition as claimed in claim 20, wherein the bioadhesive composition comprises effective amounts of at least one ionic water soluble monomer, at least one plasticiser [(]other than water[)], at least one non ionic water soluble monomer, water, at least one surfactant, and at least one hydrophobic monomer and/or polymer.

22. (Amended) A bioadhesive composition as claimed in claim 20, wherein the said reaction mixture comprises from about 5% to about 50% by weight of the reaction mixture of at least one ionic water soluble monomer, from about 10% to about 50%, by weight of the reaction mixture, of at least one plasticiser [(]other than water[)], up to about 50%, by weight of the reaction mixture, of at least one non ionic water soluble monomer, up to about 40%, by

weight of the reaction mixture, of water, up to about 10%, by weight of the reaction mixture, of at least one surfactant and from about 1% to about 30%, by weight of the reaction mixture of at least one hydrophobic monomer and/or polymer.

30. (Amended) A bioadhesive composition as claimed in claim 19, characterised in that the bioadhesive composition comprises from about 15% to about 45%, by weight of the reaction mixture of said plasticiser [(]other than water[)].